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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,462	03/03/2006	Yves Maycresse	VB60410	1403
20462	7590	09/19/2006	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				SWARTZ, RODNEY P
		ART UNIT		PAPER NUMBER
		1645		

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/533,462	MAYERESSE, YVES	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Preliminary Amendment.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-39 is/are rejected.
- 7) Claim(s) 1,12,13,14,16,18,24,27 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29April2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/16/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Applicant's Preliminary Amendment is acknowledged. Claims 1, 3-6, 8, 10-12, 14-18, 20-22, 24, 25, 27-37, and 39 have been amended.
2. Claims 1-39 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Throughout the specification there are references to "step b", "step c", e.g., page 13, line 31. However, there is no recitation of a "step a". Clarification is required.

Page 1, line 6, "stabilising" should be "stabilizing"; line 21, "lyophilised" should be "lyophilized"; line 32, "stabilising" should be "stabilizing".

Page 2, line 1, "lyophilisation" should be "lyophilization"; line 21, "stabilising" should be "stabilizing"; line 28, "stabilises" should be "stabilizes"; line 29, "stabilising" should be "stabilizing"; line 32, "lyophilisation" should be "lyophilization".

Page 3, line 6, "stabilising" should be "stabilizing".

Page 4, line 13, "stabilising" should be "stabilizing".

Page 5, line 11, "recognised" should be "recognized"; line 19, "analyser" should be "analyzer".

Page 6, lines 6, 8, 18, and 19, "stabilising" should be "stabilizing".

Page 7, lines 14, 18, 20, 23, and 24, "stabilising" should be "stabilizing"; line 17, "hydrolysed" should be "hydrolyzed".

Page 8, lines 15 and 16, "siliconisation" should be "siliconization"; line 17, "siliconised" should be "siliconized"; line 17, "rising" should be "rinsing".

Page 9, line 1, "stabilising" should be "stabilizing"; line 20, "solubilise" should be "solubilize".

Page 10, line 18, "visualisation" should be "visualization".

Page 12, lines 6 and 31, "analyser" should be "analyzer"; line 31, there are two periods at the end of the sentence.

Page 13, lines 13 and 28, "analyser" should be "analyzer".

Page 14, lines 18 and 19, "tranquillisers" should be "tranquillizers"; line 23, "peropheral" should be "peripheral".

Page 18, line 21, "particularised" should be "particularized".

Page 19, lines 9-10, "Haemophilus influenzae" and "N. meningitidis" should be in italics.

Page 20, line 24, "derivatised" should be "derivatized".

Page 21, line 2, "derivatised" should be "derivatized".

Page 25, line 15, "comprise a molecules" should be "comprise molecules"; line 19, delete "comprising".

Page 28, line 3, "carried our using" should be "carried out using".

Page 29, line 17, "sample have" should be "sample has".

Page 30, line 1, "was place on" should be "was placed on"; line 9, what is meant by "Such samples"; line 14, "stabilising" should be "stabilizing"; line 15, "siliconised" shoud be "siliconized".

Page 31, line 10, "retention compares very" should be "retention compare very".

Page 33, line 1, "table 5" should be "Table 5"; "responant" should be "respondant"; line 30, "stabilising" should be "stabilizing".

Page 34, line 6, "immunoneutralisation" should be "immunoneutralization"; line 7, "immunoneutralising" should be "immunoneutralizing".

Page 35, lines 3, 4, 7, "stabilising" should be "stabilizing"; line 5, "analyser" should be "analyzer"; line 10, "looses" should be "loses".

Abstract, line 4, "stabilising" should be "stabilizing"; line 5, "looses" should be "loses".

Appropriate correction is required.

Claim Objections

4. Claim 1 is objected to because of the following informalities: line 4, "stabilising" should be "stabilizing"; line 6, "looses" should be "loses". Appropriate correction is required.
5. Claim 12 is objected to because of the following informality: line 1, "stabilising" should be "stabilizing". Appropriate correction is required.
6. Claim 13 is objected to because of the following informality: line 1, "stabilising" should be "stabilizing". Appropriate correction is required.
7. Claim 14 is objected to because of the following informality: line 2, "stabilising" should be "stabilizing". Appropriate correction is required.
8. Claim 16 is objected to because of the following informality: line 1, "claims" should be "claim". Appropriate correction is required.
9. Claim 17 is objected to because of the following informality: line 1, "claims" should be "claim". Appropriate correction is required.
10. Claim 24 is objected to because of the following informality: line 2, "claims" should be "claim". Appropriate correction is required.
11. Claim 27 is objected to because of the following informality: line 2, "comprises" should be "comprises". Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for preserving "an" active agent comprising the steps of: preparing a preservation by dissolving or suspending "an" active agent. It is unclear if the two active agents are the same or different. If they are the same agent, the second recitation should be amended to "said active agent" or "the active agent". Claims 2-22 depend from claim 1, but do not clarify the indefiniteness.

14. Claims 3-11 are rejected under 35 U.S.C. 112, second paragraph, because the claims recite the limitations "step (b)" and "step (c)". There is insufficient antecedent basis for this limitation in the claims because claim 1 from which they depend does not recite any steps labeled "a", "b", or "c".

15. Claims 23-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a "highly" viscous liquid. The metes and bounds of what constitutes a "highly" viscous liquid versus a viscous liquid is unclear.

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16. Claims 24-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is drawn to a highly viscous liquid comprising an active agent. Claims 24-39 which are dependent from claim 23 merely recite, "The highly viscous liquid of claim 23". It is unclear claims 24-39 are only claiming the liquid, or the highly viscous liquid composition comprising an active agent. If the claims are to be drawn to the second interpretation, it is recommended that claims 23-39 be amended to recite "highly viscous liquid composition".

17. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from claim 1. Therefore, the claim is drawn to a method of preserving an active agent comprising the step of subjecting the preservation sample to such temperature and pressure conditions so that the preservation sample loses solvent by evaporation, "with freezing or bubbling involved in foam formation".

Claim 3 is drawn to the criterion that "the pressure is reduced to 20 mbars or below during step b)". However, Table 1 indicates that 0.75 mBar and less pressure results in freezing. Thus, it is unclear how one uses pressure "below 20 mbars during step b)" without freezing.

18. Claims 23-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is drawn to a highly viscous liquid comprising an active agent wherein the "antigenicity or activity of the active agent is preserved". This language indicates that there is no loss of "antigenicity or activity of the active agent". However, Table 2 indicates that at best, one loses only 7% of antigenicity. Thus, it is unclear how "antigenicity or activity of the active agent is preserved" is all of the experiments presented in the specification appear to show that there is a loss of activity no matter what the conditions. Claims 24-39 depend from claim 23, but do not clarify the issue.

19. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of preservation or a composition comprising a highly viscous liquid and an active agent, wherein a stabilizing agent is chosen from a group of glass forming polyols and utilized at a variety of concentrations. However, the specification teaches only sucrose and trehalose as the polyol, and that any concentration less than 10% resulted in 100% loss of activity of the active agent (Table 2). It is unclear how any concentration of sucrose or trehalose less than 10% preserves the activity of the active agent.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 23-33, 36-39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 14, 15-18, and 20 of copending Application No. 10/533,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions and methods of making said compositions, wherein the composition is a highly viscous liquid comprising active agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 23, 27, 28, 29, 31, 35, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Higuchi (U.S. Pat. No. 3,929,132).

The claims are drawn to "A highly viscous liquid comprising an active agent wherein the antigenicity or activity of the active agent is preserved. Higuchi teach a highly viscous liquid comprising an active agent (col. 2, lines 35-39: col. 8, lines 14 to col. 10, line 6; col. 11, lines

28-44), and a dispensing head, i.e., a kit, as well as a method for making a vaccine comprising the step of reconstituting the highly viscous liquid in an aqueous solution (Fig. 1; Example 5).

Conclusion

24. No claims are allowed.
25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert M. Navarro, can be reached on (571)272-0861.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

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September 16, 2006